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### **REMARKS/ARGUMENTS**

Claims 54-58, 60-65, 67-72, 75-80, 82, 97-105, and 119-125 were pending in the application. Claims 54-57, 70, 72, 80, and 119-124 have been cancelled. Claims 58, 67, 68, 69, 71, 82, 97, 105, and 125 have been amended. Support for the amendments can be found in the original claims as well as in the specification, particularly on pages 2, 4, and 13, and in Figure 5. No new matter has been added by way of amendment. Reexamination and reconsideration of the claims are respectfully requested.

Applicants acknowledge with appreciation the withdrawal of the rejections of claims under 35 U.S.C. § 112, first and second paragraphs, as listed in the Office Action on pages 3 and 4.

# The Rejection of Claims Under 35 U.S.C.§112, First Paragraph, Should Be Withdrawn

Applicants appreciate the Examiner's efforts to clarify the previous enablement rejection by dividing it into several rejections, and those rejections will be addressed here in the same order in which they were raised in the Office Action.

The Office Action (10/15/03, page 4, #12) has maintained the rejection of claims 54-57, 67, 68, 82, 119-124, and 125 under 35 U.S.C. §112, first paragraph, for lack of enablement "due to the requirement of alteration of at least 10% of the amino acid content of the protein...."

Applicants note that claims 54-57 and 119-124 have been canceled. Claims 67, 68, 82, and 125 have been amended, as have the independent claims from which they depend, namely, claims 58, 69, and 97. Claims 67, 82, and 125 now specify that said amino acid changes alter the content of amino acids by at least 8.25%, which as the Office Action acknowledges is the amount of alteration illustrated by a working example in the specification (see Office Action page 5, first full paragraph). Claim 68 is drawn to the method of claim 58 wherein said vegetative storage protein is  $VSP\beta$ , and claim 58 specifies that the amino acid content is altered by at least 5%. Thus, none of the currently pending claims contain a limitation wherein the

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amino acid content of the protein is altered by at least 10%. Accordingly, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 5, #13) has maintained the rejection of claims 54-57, 69-72, 75-80, 82, and 120-124 under 35 U.S.C. §112, first paragraph, for lack of enablement "due to the requirement of using interacting molecules, even specifically antibodies, with *any* protein of interest...." (emphasis in original)

Applicants note that claims 54-57, 70, 72, 80, and 120-124 have been canceled. Independent claims 58, 69, and 97 have been amended, and accordingly claims 71 (which now depends from claim 58) as well as claims 75-79 and 82 (which depend from or incorporate the limitations of claim 69) have also been amended in the same manner. Independent claims 58 and 97 involve the use of antibodies and specify that the method is for altering the amino acid composition of a vegetative storage protein. Independent claim 69 involves the use of VSP $\alpha$  and/or VSP $\beta$  to assess whether the engineered VSP $\beta$  has the conformation of the native VSP $\beta$  and specifies that the method is for altering the amino acid composition of VSP $\beta$ . Thus, none of the currently pending claims contain the limitation objected to in the Office Action. Support for the amendments is found in the specification, particularly, for example, on page 13. Accordingly, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 6, #14) has rejected claims 54, 57, 58, 60-64, 68, 69, 72, 75-80, 82, and 120-124 under 35 U.S.C. §112, first paragraph, for lack of enablement "due to the requirement of using *any* interacting molecules...." (emphasis in original)

Applicants note that claims 54, 57, 72, 80, and 120-124 have been canceled. Independent claim 58 has been amended, and therefore claims 60-64 and 68 which depend from or incorporate the limitations of claim 58 have also been amended in the same manner. Similarly, independent claim 69 has been amended, and therefore claims 75-79 and 82 which depend from or incorporate the limitations of claim 69 have also been amended in the same manner. Independent claim 58 specifies that the method comprises assessing the conformation of said engineered protein based on its ability to bind with a set of antibodies. Independent claim 69

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specifies that the method comprises assessing the conformation of engineered VSP $\beta$  based on its ability to bind with native VSP $\alpha$ , VSP $\beta$ , or both. As acknowledged in the Office Action (page 6, first paragraph), the specification provides examples in which protein conformation is assessed by using antibodies specific for VSP and using VSP homodimers and heterodimers (see, e.g., page 13 of the specification). As described above, none of the currently pending claims contain the limitation objected to in the Office Action. Accordingly, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 7, #15) has rejected claims 54-58, 60-65, 67-72, 75-80, 82, 97-105, and 119-125 under 35 U.S.C. §112, first paragraph, for lack of enablement "due to the requirement of using a set of antibodies to <u>determine</u> VSP protein conformation...." (emphasis in original)

Applicants note that claims 54-57, 70, 72, 80, and 119-124 have been canceled. Independent claim 58 has been amended, and therefore claims 60-65, 67, 68, and 71 which depend from or incorporate the limitations of claim 58 have also been amended in the same manner. Independent claim 69 has been amended, and therefore claims 75-79 and 82 which depend from or incorporate the limitations of claim 69 have also been amended in the same manner. Independent claim 97 has been amended, and therefore claims 98-105 and 125 which depend from or incorporate the limitations of claim 97 have also been amended in the same manner. Specifically, independent claims 58, 69, and 97 now specify that the method comprises the step of assessing whether the engineered protein of the claim has the conformation of the native protein of the claim. Support for this amendment is found in the specification, particularly on pages 2, 4, and 13. As described above, none of the currently pending claims contain the limitation objected to in the Office Action. Accordingly, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 9, #19) has rejected claims 54, 57, 58, 60-65, 67, 69, 72, 75-80, 82, and 119-124, under 35 U.S.C. §112, first paragraph, "new matter, as failing to

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comply with the written description requirement," for their recitation of "a set of interacting molecules."

Claims 54, 57, 72, 80, and 119-124 have been canceled. Independent claim 58 has been amended, and therefore claims 60-65 and 67 which depend from or incorporate the limitations of claim 58 have also been amended in the same manner. Independent claim 69 has been amended, and therefore claims 75-79 and 82 which depend from or incorporate the limitations of claim 69 have also been amended in the same manner. As amended, independent claim 58 is drawn to a method involving a step in which a set of antibodies is used to assess the conformation of an engineered vegetative storage protein. As amended, independent claim 69 is drawn to a method involving a step in which VSP $\alpha$ , VSP $\beta$ , or both are used to assess the conformation of an engineered VSP $\beta$ . As acknowledged in the Office Action, the originally-filed specification supports methods using sets of antibodies as well as interacting molecules that are homodimers or heterodimers of VSP $\alpha$  and VSP $\beta$ .

Thus, as discussed above, none of the currently pending claims contain the limitation objected to in the Office Action, and support is found in the specification for the claims as amended. Accordingly, this rejection has been obviated by amendment and should be withdrawn.

# The Rejection of Claims Under 35 U.S.C.§112, Second Paragraph, Should Be Withdrawn

There were several of these rejections in the Office Action. These rejections will be addressed here in the same order in which they were raised in the Office Action.

The Office Action (10/15/03, page 4, #10) has maintained the rejection of claim 123 as being indefinite. Because this claim has been canceled, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 8, #17) has rejected claims 57, 58, 60-65, 67, 72, and 119 as being indefinite for their recitation of "set of interacting molecules" in relation to "homodimer." Claims 57, 72, and 119 have been canceled. Independent claim 58 has been

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amended to remove the phrase "set of interacting molecules," and therefore claims 60-65 and 67 which depend from or incorporate the limitations of claim 58 have also been amended in this manner. Accordingly, because none of the currently pending claims contain the limitations objected to in the Office Action, this rejection has been obviated by amendment and should be withdrawn.

The Office Action (10/15/03, page 8, #18) has rejected claim 65 as being indefinite due to specified limitations in independent claim 58. Independent claim 58 has been amended and no longer contains the limitation that interacting molecules form homodimers or heterodimers with the protein of interest. Rather, independent claim 58 now contains a method step of assessing the conformation of said engineered protein based on its ability to bind with a set of antibodies. As amended, the limitations of claim 65 involving filter lift assay and ELISA correspond to the limitations in claim 58. Therefore, this rejection has been obviated by amendment and should be withdrawn.

#### The Objection to Claim 57 Should Be Withdrawn

The Office Action (10/15/03, page 7, #16) is objected to for having improper form. Because this claim has been canceled, this objection has been obviated by amendment and should be withdrawn.

### Consideration Of Previously Submitted Information Disclosure Statement

It is noted that an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement filed August 14, 2003, was not considered by the Examiner due to non-payment of the appropriate fee. Applicants have submitted the appropriate fee as required. Accordingly, it is requested that an initialed copy of the Form 1449 be forwarded to the undersigned with the next communication from the PTO. Copies of the cited references were provided at the time of filing the original Information Disclosure Statement, and, therefore, no additional copies of the references are submitted herewith. Applicants will be

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pleased to provide additional copies of the references upon the Examiner's request if it proves difficult to locate the original references.

#### CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§112, first and second paragraphs, and the objection to the claims, are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450

Lynda-Io Pixley